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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/058,967	01/30/2002	Eric R. Cosman	11747-009001	4492

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Steptoe & Johnson LLP
1330Conn Avenue N. W.
Wash., DC 20036

EXAMINER

VRETTAKOS, PETER J

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/058,967

Applicant(s)

COSMAN, ERIC R.

Examiner

Peter J Vrettakos

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-29, 31-33, 35-37 is/are rejected.
- 7) ☒ Claim(s) 12, 30 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- *Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

An RCE was filed 11-23-04.

Prior rejections have been obviated. New rejections are presented below.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-3, 7-11, 14-19, 25-29 and 32-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Schaer (US 5,782,760).

Independent claims 1, 11, 14, 17, and 28

A device for ablating tissue in the living body comprising:

a guide element (31); and

an elongate member (10) defining a longitudinal passage (14) having a distal opening and a proximal opening dimensioned (see figures 3 and 5) to pass along and over the guide element (31) directed into the tissue, the elongated member including an electrode (17, 18 - sensing) disposed at a distal portion of the elongate member and configured to be energized with high frequency energy to ablate tissue (see Abstract).

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14. A device for ablating tissue comprising:

a guide element (31);

a flexible elongate tubular member (10) defining a longitudinally extending lumen (14) having a distal opening and a proximal opening, the lumen dimensioned to pass along and over the guide element directed into the tissue, a distal portion of the tubular member having a blunt distal tip (rounded tip depicted in figure 1);

an electrode (17,18) disposed at a distal portion of the tubular member and configured to be energized with high frequency energy to thermally ablate the tissue (Abstract); and

a fluid channel (see col. 5:40-48) within the tubular member, the fluid channel in fluid communication with a fluid input port (29) and a fluid output port (36, figure 5) and in thermal communication with the electrode (fluid cools the electrode – col. 5:40-48).

17. A system for ablation of tissue in the living body comprising:

a guide element (31); and an ablation system including:

an elongate member (10) defining a longitudinal channel (14) having a distal opening and proximal opening, the elongate member being dimensioned to slide along and over the guide element directed into the tissue; and

an electrode (17) at a distal portion of the elongate member and configured to be energized with high frequency energy to ablate the tissue (Abstract).

28. A method for thermal ablation of a target volume comprising:

perforating and penetrating a living body using a guide element (31) to establish a tract

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through the body to the target volume;

sliding an electrode (intravascular device disclosed by Schaer) along and over the guide element directed into the body to position the electrode near the target volume, the electrode including an elongate member defining a longitudinal passage dimensioned to pass along the guide wire, a conductive surface at a distal portion of the elongate member, and an electrical connection between the conductive surface and a proximal portion of the elongate member; connecting the electrical connection to a high frequency generator; supplying high frequency energy from the generator through the electrode to the target volume to thermally ablate the target volume. (The method is disclosed in col. 3:43-62.)

Dependent claims (parentheticals refer to Schaer)

2. The device of claim 1 wherein the elongate member comprises a blunt distal tip (figure 1).

3. The device of claim 1 wherein:

the device further comprises a fluid inlet port and a fluid outlet port; and

the elongate member further defines a fluid channel in fluid communication with the fluid inlet port and the fluid outlet port and in thermal communication with the electrode. (This was addressed in the office action, *supra*).

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7. The device of claim 1 wherein the elongate member is flexible (the patented invention is *intravascular*).

8. The device of claim 7 wherein the electrode (17) includes a tapered contour converging with the distal opening (see figure 1).

9. The device of claim 2 wherein the elongate member is flexible (the patented invention is *intravascular*).

10. The device of claim 9 wherein the electrode is a ring (18).

15. The device of claim 14 wherein the electrode (17) includes a tapered contour converging with the distal opening (see figure 1).

16. The device of claim 14 wherein the electrode is a ring (18).

18. The system of claim 17 further comprising a needle element defining a longitudinal lumen (14) dimensioned to pass the guide element, wherein the needle includes a sharp distal tip configured to penetrate the tissue.

19. The system of claim 17 wherein the guide element comprises a flexible guide wire (the wire is part of an *intravascular* guiding catheter).

25. The system of claim 17 wherein the ablation system further comprises:

a high frequency generator; and electrical conductors connecting the high frequency generator to the electrode (see patented claim 1, section e).

26. The system of claim 17 wherein: the elongate member defines a fluid channel in fluid communication with a fluid input and a fluid outlet and in thermal communication with the electrode; and the ablation system further comprises a coolant supply connected to the fluid input (see patented claims 7 and 8).

27. The system of claim 17 wherein the ablation system further comprises a fluid agent injector (figure 1, 29).

29. The method of claim 28 further comprising cooling the electrode while supplying high frequency energy to change a spatial distribution of heat near the electrode, cooling including connecting a source of a coolant to a fluid input and causing a coolant to flow in a fluid channel in the elongate member, the fluid channel being in fluid communication with the fluid input and a fluid output and in thermal communication with the electrode (see patented claims 7 and 8).

32. The method of claim 28 further including dilating the tissue along the tract after positioning the guide wire by passing a dilating element (43, figure 11, col. 6:38-47) over

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the guide wire to expand the tissue along the tract prior to sliding the electrode along the guide wire.

33. The method of claim 28 further comprising introducing a fluid agent (cooling fluid) through the guide element (patented claims 7 and 8).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 4-6, 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer.

Schaer discloses an intravascular device, which is inherently flexible to permit passage through the vasculature.

However, Schaer also discloses in col. 7:61-65 that the patented invention can be made of PEBAX and other thermoplastic materials. The Office contends that these materials are characterized across a wide hardness spectrum ranging from flexible to rigid. As a result, it would have been obvious to one of ordinary skill in the art at the time of the

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invention to modifying Schaer by designing a more rigid over the wire device. The motivation would be to increase the number of applications for which the device is able to perform.

4. The device of claim 2 wherein:

the elongate member is **rigid** (see parentheticals arguments above); and the blunt distal tip converges smoothly with the distal opening (see the rounded tip in figure 1).

5. The device of claim 4 wherein;

the blunt distal tip comprises a rounded contour surrounding the distal opening (see figure 1).

6. The device of claim 4 wherein the blunt distal tip comprises a tapered contour converging with the distal opening (see figure 1).

13. The device of claim 11, wherein:

the tubular member comprises a plastic tube (col. 7:60-63); and the electrode comprises a metal element (col. 7:66-67).

Claims 20-25, 27, 31 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schaer in view of Panescu (5,688,267).

Schaer neglects to expressly disclose anchoring means.

Panescu et al. (Panescu) discloses an analogous device, amongst several embodiments, and method for tissue ablation comprising:

an elongate/tubular member (figure 15; element 22) with longitudinal passage/lumen dimensioned to pass a guide element (126),

the elongate/tubular member including an electrode (16) disposed at a distal portion of the elongate member;

a fluid channel (64) and port (44) in thermal communication with the electrode.

Note: the elongate member (22) and the electrode (16) are depicted in figure 15a as contiguous/seamless.

Re: claim 20, Panescu discloses a rigid stylet wire (126, col. 19:23-25) – includes a stainless steel sleeve (128).

Re: claims 21-24, and 31, Panescu depicts an anchor (150) in figure 15c.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify Schaer in view of Panescu by including an anchoring means to permit securing the distal end of the device to the targeted tissue (or its periphery).

Re: claim 25, Panescu depicts a generator (12) and an electrical conductor (32) in figure 2a.

Re: claims 27, Panescu discloses fluid inlet (54) and outlet (72) ports, a fluid source (50), and injector (56) in figure 19.

Re: claims 35-37, Panescu depicts in figure 15a the fluid output port (44) at a proximal portion of the elongate member (22).

Allowable Subject Matter

Claim 12, 30 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J Vrettakos whose telephone number is 703 605 0215. The examiner can normally be reached on M-F 9-6.

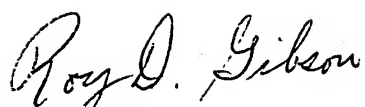
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C Dvorak can be reached on 703 308 0994. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 308 0858.

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Pete Vrettakos
March 5, 2005


ROY D. GIBSON
PRIMARY EXAMINER